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EXAMINER
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ART UNIT	PAPER NUMBER
3626	

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Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)
Office Action Summary	09/699,372	HUDSON, COURTNEY
	Examiner	Art Unit
	Rachel L. Porter	3626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE <u>3</u> MONTH(S) FROM
THE MAILING DATE OF THIS COMMUNICATION.
- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed
  after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any
  earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 October 2000, 2/14/02, and 1/15/03*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is
closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

    4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

    Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

    a)☐ All b)☐ Some * c)☐ None of:

      1.☐ Certified copies of the priority documents have been received.

      2.☐ Certified copies of the priority documents have been received in Application No. _____.

      3.☐ Copies of the certified copies of the priority documents have been received in this National Stage
application from the International Bureau (PCT Rule 17.2(a)).

    * See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application)
since a specific reference was included in the first sentence of the specification or in an Application Data Sheet.
37 CFR 1.78.

    a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific
reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4-5*

4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .

5) ☐ Notice of Informal Patent Application (PTO-152)

6) ☐ Other: .

DETAILED ACTION

Notice to Applicant

1. This communication is in response to the communications filed 10/31/00, 2/14/02 and 1/15/03. Claims 1-24 are pending. The IDS's filed 2/14/02 have been entered and all documents published in the English language have been considered. (See below regarding EP0936566 A2.)

Information Disclosure Statement

2. The information disclosure statement filed 1/15/2003 fails to comply with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each patent listed that is not in the English language. It has been placed in the application file, but the information referred to therein has not been considered.

Specification

3. The disclosure is objected to because of the following informalities: the brief description of drawings for Figure 3 should indication that the figure includes several parts (i.e. FIG. 3A-3D). Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly
> claiming the subject matter which the applicant regards as his invention.

5. Claim 7 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. Claim 7 recites the limitation "*the* static questions" in line 1. There is insufficient antecedent basis for this limitation in the claim. Claims 1-3,6 do not recite the use of static, dynamic, or targeted questions.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 1-8, 10-14,17-24 are rejected under 35 U.S.C. 102(e) as being anticipated by Michelson et al (USPAN 2002/0002474).

[claim 1] Michelson teaches a method for matching patients with clinical trials, comprising:

-   receiving patient profile information for a patient at a server connected to a computer

    network, the patient profile information submitted by a user at a terminal connected

    to the network, (par. 80,89-94; Figure 2A/2B-6B)

-   comparing the patient profile information with acceptance criteria for clinical trials

    stored in a database, the comparison performed by the server; and (par. 80-83; 105,

    166-170; Figure 14)

-   determining whether the patient prequalifies for any of the clinical trials; and (par.

    113; 166-170; figure 14)

-   notifying the user whether the patient has prequalified for any clinical trial. (par. 113;

    168-170)

[claim 2] Michelson teaches a method, wherein the steps of comparing, determining,

and notifying comprise:

-   comparing the patient profile information with acceptance criteria for clinical trial

    sites stored in a database, the comparison performed by the server; (par. 80-83,105,

    166-170; Figure 14)

-   determining whether the patient prequalifies for any of the clinical trial sites; and

    (par. 113; 166-170; figure 14)

-   notifying the user whether the patient has prequalified for any clinical trial sites. (par.

    113)

[claim 3]   Michelson teaches the method of claim 2, further including providing the user

with instructions for enrolling in the clinical trial for which the user has prequalified. (par.

162-163, 171)

[claim 4] Michelson teaches the method of claim 2, further including:

- asking the user a plurality of questions; and (par. 80-83; 162-170)

- creating a patient profile based on the responses to the plurality of questions. (par.

   162-163)

[claim 5] Michelson teaches a method wherein the step of asking the user a plurality of

questions includes:

- asking the user one or more static questions; (par. 162-163)

- asking the user one or more dynamic questions which are selected based on the

   user's responses to other static and dynamic questions; and (par. 162-167)

- creating a patient profile based on the responses to the static and dynamic

   questions. (par. 83,169)

[claim 6] Michelson teaches the method of claim 3, further including:

- asking the user a series of questions targeted to a specific clinical trial site after

   determining that a patient meets preliminary acceptance criteria for the specific

   clinical trial; and (par. 168-169)

- determining whether the user prequalifies for the specific clinical trial based on the

   user's response to the targeted questions. (par. 168-169)

[claim 7] Michelson teaches the method of claim 6, wherein the static questions,

dynamic questions, and targeted questions are provided with a plurality of answer

options, and the user may select one or more answer options in order to answer the

questions. (figures 4A-4C; par. 83)

[claim 8] Michelson teaches the method of claim 7, wherein the user is required to submit an answer in a specified format, the specified format being suitable for evaluation by a computer program process. (figures 4A-4C; par. 83)

[claim 10]   Michelson teaches the method of claim 1, wherein the network is the Internet. (par. 80-83; 89-91)

[claim 11]   Michelson teaches the method of claim 1, wherein the user is provided with an application to submit for a clinical trial for which the patient has prequalified. (par. 167-168)

[claim 12]   Michelson teaches the method of claim 11, wherein the application is filled out by the user and submitted on-line to the server. (par. 89-98, 102, and 162-170)

[claim 13]   Michelson teaches the method of claim 12, wherein the application is forwarded to the clinical trial site. (par. 165-170)

[claim 14]   Michelson teaches the method of claim 13, wherein the patient profile is forwarded to the clinical trial site with the application. (par, 166-170)

[claim 17]   Michelson teaches the method of claim 1, wherein the user is provided with a search engine that allows the user to search for medical information before selecting a clinical trial. (par. 92-94)

[claim 18]   Michelson teaches the method of claim 1, wherein the acceptance criteria include geographic location. (par. 167)

[claim 19] Michelson teaches a system for matching patients with clinical trials comprising:

- a server connected to a network; (par. 80; Figures 1A-1B)

- a data storage device included in the server; and (par. 80-83)

- a database located in the data storage device, the database storing patient profile

   information for a patient and acceptance criteria for a plurality of clinical trials; (par.

   80-83)

- the server comparing the patient profile information with the acceptance criteria for

   the clinical trials stored in the database, determining whether the patient prequalifies

   for any of the clinical trials, and notifying a user whether the patient has prequalified

   for any clinical trials. (par. 80-83; par. 113)

[claim 20] Michelson teaches system of claim 19, wherein the database contains at

least one of: a) disease/sub-disease records; b) drug records; c) content records; d)

clinical trial records; e) question records; f) device records; g) patient profile records;

h) user registration records; and i) trial site records. (par. 82-84; 87-88)

[claim 21] Michelson teaches the system of claim 20, wherein a record in the database

contains links to other related records.(par. 88)

[claim 22] Michelson teaches the system of claim 20, wherein the server transmits a

plurality of questions to the user over the network, the server also transmits a plurality of

answer choices for each question, the server receives responses from the user, and the

server builds a patient profile based on the responses. (par. 80-83, 87)

[claim 23] Michelson teaches a system wherein the server retrieves a disease/sub-

disease record corresponding to a disease/sub-disease entered by the user, the

disease/sub-disease record containing links to question records, the server retrieving

the question records to access questions to be provided to the user. (par. 80, 82-83, 87)

[claim 24] Michelson teaches computer executable software code stored on a computer

readable medium, performing a method for matching patients with clinical trials,

comprising:

- receiving patient profile information for a patient at a server connected to a computer

  network, the patient profile information submitted by a user at a terminal connected

  to the network; (par. 80, 89-94; Figure 2A/2B-6B)

- comparing the patient profile information with acceptance criteria for clinical trials

  stored in a database, the comparison performed by the server; and (par. 80-83; 105,

  166-170; Figure 14)

- determining whether the patient prequalifies for any of the clinical trials; (par. 113;

  166-170; figure 14) and

- notifying the user whether the patient has prequalified for any clinical trials. (par.

  113; 168-170)

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all

obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set
> forth in section 102 of this title, if the differences between the subject matter sought to be patented and
> the prior art are such that the subject matter as a whole would have been obvious at the time the
> invention was made to a person having ordinary skill in the art to which said subject matter pertains.
> Patentability shall not be negatived by the manner in which the invention was made.

10. Claims 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Michelson

in view of Altman et al (USPN 5,572,421).

[claim 9] Michelson teaches the method of claim 8 as explained in the rejection of claim

8, but does not expressly disclose that the questions asked of the user are updated.

Altman discloses a method wherein patient question are updated periodically. (col. 9,

lines 42-48) At the time of the Applicant's invention, it would have been obvious to one

of ordinary skill in the art to modify the method of Michelson with the teaching of Altman

to periodically update the patient questions. As suggested by Altman, one would have

been motivated to include this feature to keep up the progress of medical knowledge.

(Altman: col. 4, lines 19-22)

11. Claims 15-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over

Michelson in view of Kraftson et al (USPN 6,151,581).

[claim 15] Michelson teaches a method for matching patients with clinical trials as

explained in the rejection of claim 14. Michelson further discloses storing patient

profiles (par. 98, 190-191) and wherein patient privacy is guarded (par. 30), but does

not expressly disclose that the patient record and application include a patient ID to

conceal the patient's identity. Kraftson teaches a system/method wherein a random ID

number is assigned to a patient's profile and questionnaire to conceal/protect the

patient's identity. (col. 12, lines 53-62) At the time of the Applicant's invention, it would

have been obvious to one of ordinary skill in the art to modify the method of Michelson

with the teaching of Kraftson to store the patient's information with a patient ID number.

As suggested by Kraftson, one would have been motivated to include this feature to

ensure that the patient is free to answer questions honestly and accurately with fear that

his/her information will be divulged. (col. 12, lines 35-49)

[claim 16] Michelson teaches a method further including notifying the clinical trial

sponsor when the user submits an application to the clinical trial site. (par. 108-112)

Conclusion

12. The prior art made of record and not relied upon is considered pertinent to

applicant's disclosure.

- Anonymous (" How to Keep Rolling in Enrollment") discloses techniques for

    increasing enrollment in clinical trials.

Any inquiry concerning this communication or earlier communications from the

examiner should be directed to Rachel L. Porter whose telephone number is 703-305-

0108. The examiner can normally be reached on M-F, 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, Joseph Thomas can be reached on (703)305-9588. The fax phone number

for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or

proceeding should be directed to the receptionist whose telephone number is (703)308-

1113.

RP